

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1. (currently amended): A pharmaceutical formulation comprising a free-flowing plurality of particles comprising a pharmaceutically active agent and an excipient, wherein the formulation includes one or more tastemasking agents incorporated into the formulation so that the taste intensity of the ~~flavouring~~ tastemasking agents substantially always exceeds the taste intensity of the active agent, without significantly affecting the dissolution profile of the formulation.

Claim 2. (currently amended): A pharmaceutical formulation as claimed in claim 1, wherein said particles each include both the active agent and the excipient.

Claim 3. (original): A pharmaceutical formulation as claimed in claim 2, wherein the particles comprise a core and a coating that includes a quantity of the excipient.

Claim 4. (original): A pharmaceutical formulation as claimed in claim 3, wherein the coating is a continuous coating, surrounding the core.

Claim 5. (currently amended): A pharmaceutical formulation as claimed in claim 1 ~~any of the preceding claims~~, wherein the particles are formed by melt-coating core particles with a coating material that includes a quantity of the excipient, at a temperature below the melting point or decomposition temperature of the active agent.

Claim 6. (currently amended): A pharmaceutical formulation as claimed in claim 5, wherein the core particles are 10 to 1000µm in size, ~~preferably 200 to 600µm or 100 to 300µm.~~

Claim 7. (currently amended): A drug formulation as claimed in claim 5 ~~or 6~~, wherein the size of the excipient particles used to melt-coat the core particles ~~are~~ is 10% or less than the size of the core particle.

Claim 8. (currently amended): A pharmaceutical formulation as claimed in claim 3 ~~any of claims 3-7~~, wherein a quantity of the active agent is included in the core ~~or core particles~~.

Claim 9. (currently amended): A pharmaceutical formulation as claimed in claim 1 ~~any one of the preceding claims~~, wherein the formulation includes one or more sweeteners and/or flavouring agents.

Claim 10. (currently amended): A pharmaceutical formulation as claimed in claim 3 ~~claim 3-9~~, wherein a quantity of the ~~sweeteners and/or flavouring~~ tastemasking agents is included in the coating ~~or coating material~~.

Claim 11. (currently amended): A pharmaceutical formulation as claimed in claim 3 ~~any one of the preceding claims~~, wherein the core ~~or core particles are~~ is not pre-coated with a release retarding coating.

Claim 12. (currently amended): A pharmaceutical formulation as claimed in claim 3 ~~any of claims 3-11~~, wherein the coating ~~or coating material~~ further comprises a water soluble or hydrophilic binder.

Claim 13. (currently amended): A pharmaceutical formulation as claimed in claim 3 ~~any of claims 3-12~~, wherein the coating ~~or coating material~~ further comprises a hydrophobic binder.

Claim 14. (currently amended): A pharmaceutical formulation as claimed in claim 12 ~~or 13~~, wherein the binder melts or softens sufficiently to melt-coat the core particles at a temperature below the melting point or decomposition temperature of the active agent.

Claim 15. (currently amended): A pharmaceutical formulation as claimed in claim 3 ~~any of claims 1-13~~, wherein the excipient melts or softens sufficiently to melt-coat the core particles at a temperature below the melting point or decomposition temperature of the active agent.

Claim 16. (original): A pharmaceutical formulation as claimed in claim 14, wherein the binder melts or softens sufficiently to melt-coat the core particles at a temperature below the melting point or decomposition temperature of the excipient.

Claim 17. (currently amended): A pharmaceutical formulation as claimed in claim 3 ~~any of the preceding claims~~, wherein the core or core particles include a water soluble excipient.

Claim 18. (currently amended): A pharmaceutical formulation as claimed in claim 1 ~~any of the preceding claims~~, formed by a process in which the active agent is not raised to or above its melting point, or a temperature at which a significant proportion thereof is caused to decompose.

Claim 19. (original): A pharmaceutical formulation as claimed in claim 17, wherein the water soluble excipient is one or more of: sugars, sugar alcohols, polyethylene glycols (PEGs), polyethylene oxides, gelatin, partially hydrolyzed gelatin, hydrolyzed dextran, dextrin, alginate, sodium bicarbonate, citric acid, tartaric acid, malic acid, fumaric acid, adipic acid, succinic acid, sodium glycine carbonate and sweeteners.

Claim 20. (original): A pharmaceutical formulation as claimed in claim 19, wherein the water soluble excipient is a sugar alcohol or combination of sugar alcohols.

Claim 21. (currently amended): A pharmaceutical formulation as claimed in claim 20, wherein the sugar alcohol ~~or sugar alcohols~~ is selected from the group consisting of ~~or are~~ sorbitol, mannitol, maltitol, reduced starch saccharide, xylitol, reduced paratinose, erythritol, ~~or any and~~ combinations thereof.

Claim 22. (original): A pharmaceutical formulation as claimed in claim 12, wherein the binder includes one or more of: polyethylene glycols (PEGs), polyethylene oxides, sugar alcohols, stearic acid, glyceryl monostearate, glyceryl palmitostearate and suppository bases.

Claim 23. (currently amended): A pharmaceutical formulation as claimed in claim 3 ~~any of claims 2-22~~, wherein the core ~~or core particles include~~ includes an additional excipient for controlling or delaying the release of the active agent.

Claim 24. (currently amended): A pharmaceutical formulation as claimed in claim 23, wherein the core ~~or core particles include~~ includes a layer or coating of said additional excipient encapsulating an inner core comprising the active agent.

Claim 25. (currently amended): A pharmaceutical formulation as claimed in claim 23 ~~or 24~~, wherein said additional excipient provides an enteric or sustained release coating.

Claim 26. (original): A pharmaceutical formulation as claimed in claim 25, wherein said additional excipient is selected from the group consisting of cellulose acetate phthalate, hydroxypropylmethylcellulose phthalate, polymethacrylates, shellac, ethylcellulose, hydroxypropylcellulose, and hydroxypropylmethylcellulose.

Claim 27. (currently amended): A pharmaceutical formulation as claimed in claim 1 ~~any of the preceding claims~~, wherein said formulation dissolves in a patient's mouth within 30 or 15 seconds after administration without the coadministration of a fluid.

Claim 28. (currently amended): A pharmaceutical formulation as claimed in claim 1 ~~any of the preceding claims~~, wherein the particles comprise at least about 50% active agent.

Claim 29. (currently amended): A pharmaceutical formulation as claimed in claim 1 ~~any one of claims 1 to 27~~, wherein the particles comprise less than about 50% active agent.

Claim 30. (currently amended): A pharmaceutical formulation as claimed in claim 1 ~~any of the preceding claims~~ further comprising a low viscosity polymer.

Claim 31. (currently amended): A pharmaceutical formulation as claimed in claim 1 ~~any of the preceding claims~~ further comprising a salivary stimulant.

Claim 32. (currently amended): A pharmaceutical formulation as claimed in claim 1 ~~any of the preceding claims~~, wherein said formulation further comprises an excipient selected from the group consisting of polyvinyl alcohol, polyvinylpyrrolidine, acacia and combinations thereof.

Claim 33. (currently amended): A pharmaceutical formulation as claimed in claim 1 ~~any of the preceding claims~~ further comprising a water soluble artificial sweetener.

Claim 34. (original): A pharmaceutical formulation as claimed in claim 33, wherein said water soluble artificial sweetener is selected from the group consisting of soluble saccharin salts, such as sodium or calcium saccharin salts, cyclamate salts, acesulfam-K, the free acid form of saccharin and mixtures thereof.

Claim 35. (currently amended): A pharmaceutical formulation as claimed in claim 1 ~~any of the preceding claims~~ further comprising a dipeptide based sweetener.

Claim 36. (original): A pharmaceutical formulation as claimed in claim 35, wherein said dipeptide based sweetener is L-aspartyl L-phenylalanine methyl ester.

Claim 37. (original): A pharmaceutical formulation as claimed in claim 31, wherein said salivary stimulant is selected from the group consisting of citric acid, tartaric acid, malic acid, fumaric acid, adipic acid, succinic acid, acid anhydrides thereof, acid salts thereof and combinations thereof.

Claim 38. (original): A pharmaceutical formulation as claimed in claim 31, wherein said salivary stimulant is an effervescent agent.

Claim 39. (original): A pharmaceutical formulation as claimed in claim 38, wherein said effervescent agent is the result of a reaction of a soluble acid source and an alkali metal carbonate or carbonate source.

Claim 40. (currently amended): A pharmaceutical formulation as claimed in claim 1 ~~any of the preceding claims~~, wherein the formulation is capable of dissolving or dispersing in a patient's mouth within 1 minute after administration without the co-administration of a fluid.

Claim 41. (currently amended): A pharmaceutical formulation as claimed in claim 1 ~~any of the preceding claims~~, arranged for direct un-encapsulated administration to the oral cavity.

Claim 42. (currently amended): A pharmaceutical formulation as claimed in claim 1 ~~any of the preceding claims~~, wherein the particles are non-compressed.

Claim 43. (currently amended): A pharmaceutical formulation as claimed in claim 1 ~~any of the preceding claims~~, wherein the a flavouring intensity substantially always exceeds the intensity of the taste of the active agent, without affecting the dissolution profile of the formulation.

Claim 44. (currently amended): A method of preparing a formulation as claimed in claim 1 ~~any one of the preceding claims~~, comprising forming the particles by melt-coating core particles with a coating material that includes a quantity of the water-soluble excipient and, optionally, a quantity of the binder, at a temperature below the melting point or decomposition temperature of the active agent.

Claim 45. (currently amended): A method of treating a human or animal patient, the method comprising preparing the drug formulation of claim 1 and administering the formulation ~~Use of a drug formulation as claimed in any of claims 1-43, or a drug formulation prepared by a method as claimed in claim 44, for the preparation of a medicament for treating a human or animal patient, wherein the formulation is administered~~ directly and in an un-encapsulated form to the patient's oral cavity.

Claim 46. (currently amended): The method of claim 45 ~~A method of treating a human or animal patient, wherein a formulation as claimed in any of claims 1-43, or a drug formulation prepared by a method as claimed in claim 44 [[,]] is administered in a un-encapsulated form directly into the patient's oral cavity.~~

Claim 47. (currently amended): A drug delivery system comprising a dosing device comprising a housing and an actuator, said device containing at least one unit dose of a drug formulation as claimed in claim 1 ~~any one of claims 1-43, or a drug formulation prepared by a method as claimed in claim 44~~, said device upon actuation delivering a unit dose of said drug formulation such that an effective dose of said drug cannot be delivered into the lower lung of a human patient.

Claim 48. (original): The drug delivery system as claimed in claim 47, wherein said at least one unit dose is contained in a reservoir.

Claim 49. (original): The drug delivery system as claimed in claim 47, further comprising a metering component to meter a unit dose from said reservoir upon actuation of said system.

Claim 50. (original): The drug delivery system as claimed in claim 47, comprising multiple unit doses, wherein said unit doses are individually metered prior to said actuation.

Claim 51. (original): The drug delivery system as claimed in claim 47, further comprising sachets, each sachet containing said individually metered unit dose.

Claim 52. (currently amended): A method ~~as claimed in~~ of treating a patient ~~comprising with an active agent for gastrointestinal deposition comprising~~ administering a formulation as claimed in claim 1 for gastrointestinal deposition.

Claim 53. (currently amended): A method as claimed in claim 44, ~~wherein said particles are prepared by a process~~ further comprising melt granulating said water soluble excipient and the

active agent to form a homogenous mixture.

Claim 54. (currently amended): A method as claimed in claim 44, ~~wherein said particles are prepared by a process~~ further comprising melt coating said water soluble excipient onto said active agent.

Claim 55. (currently amended): A method as claimed in claim ~~44~~ 53 ~~or claim 54~~, which are prepared without the use of an aqueous fluid.

Claim 56. (new): A pharmaceutical formulation as claimed in claim 6, wherein the core particles are 200 to 600 μ m in size.

Claim 57. (new): A pharmaceutical formulation as claimed in claim 6, wherein the core particles are 100 to 300 μ m in size.

Claim 58 (new): A pharmaceutical formulation as claimed in claim 13, wherein the binder melts or softens sufficiently to melt-coat the core particles at a temperature below the melting point or decomposition temperature of the active agent.

Claim 59 (new): A pharmaceutical formulation as claimed in claim 1, wherein the particles comprise at least about 60% active agent.

Claim 60 (new): A pharmaceutical formulation as claimed in claim 1, wherein the particles comprise at least about 75% active agent.